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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dawn Taylor-Mulneix at 301-767-5189, or *dawn.taylor-mulneix@nih.gov.* Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852: tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Human Monoclonal Antibodies that Broadly Target Coronaviruses.

Description of Technology:

The family of coronaviruses cause upper respiratory tract disease in humans and have caused three major disease outbreaks in recent history: the 2003 SARS outbreak, the 2012 MERS outbreak, and the current SARS-CoV-2 pandemic. There is an urgent need for strategies that broadly target coronaviruses, both to deal with new SARS-CoV-2 variants and future coronavirus outbreaks.

Scientists at NIAID have developed several novel human monoclonal antibodies that bind to conserved parts of the SARS-CoV-2 spike protein. These antibodies can neutralize SARS-CoV-2 variants of concern including Omicron BA.1 and BA.2, as well as neutralize at least one other betacoronavirus. Further, these antibodies limit disease in animal models. Broadly reactive antibodies against coronaviruses are useful tools to identify conserved sites on the coronavirus spike protein, which could be investigated for the development of broad coronavirus vaccines that aim to prevent future pandemics. Potent neutralizers that target these sites could also be useful for prevention of disease caused by diverse coronaviruses, including those that may emerge in the future.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Prophylactic usage against SARS-CoV-2 and/or other betacoronaviruses in normal or high-risk populations
- Therapeutic treatment, alone or in combination, in patients with SARS-CoV-2 and/or other betacoronaviruses infections.
- Assay development for surveillance, diagnostic, and prevention measures

Competitive Advantages:

- Antibodies can neutralize SARS-CoV-2 variants, including Omicron BA.1 and BA.2
- Antibodies can broadly target and neutralize betacoronaviruses

Development Stage:

- Pre-Clinical

Inventors: Joshua Tan, Ph.D., Cherrelle Dacon, Ph.D., both of NIAID.

Publications: Dacon, C., et al. "Broadly neutralizing antibodies target the coronavirus fusion peptide" *bioRxiv* 2022.04.11.48789. Doi: https://doi.org/10.1101/2022.04.11.48789
(This article is a preprint and has not been certified by peer review)

Intellectual Property: HHS Reference No. E-047-2022-0-EIR-00 U.S. Patent Application No. 63/308,898, filed on February 10, 2022.

Licensing Contact: To license this technology, please contact Dawn Taylor-Mulneix at 301-767-5189, or *dawn.taylor-mulneix@nih.gov*, and reference E-047-2022.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Areas of specific interest include (a) testing developability of these antibodies (e.g., biophysical characteristics, cross-reactivity, pharmacokinetics, toxicity), (b) pre-clinical model assessment, and (c) human clinical trials. For collaboration opportunities, please contact Dawn Taylor-Mulneix at 301-767-5189, or *dawn.taylor-mulneix@nih.gov.*

Date: June 3, 2022.

Surekha Vathyam,

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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